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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

dicant:

Michael R. Hayden et al.

Art Unit:

1616

DEC 08 2000

PRADEMA Serial No .:

09/654,323

Examiner:

TECH CENTER 1600/2900

Filed:

September 1, 2000

Title:

Compositions and Methods for Modulating HDL Cholesterol and Triglyceride

Assistant Commissioner For Patents

Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the attached form PTO 1449. Submission of this statement is not a representation that a search has been made nor is information included in this statement an admission that the information is material to patentability.

Under 35 USC 120, this application relies on the earlier filing date of application serial number 09/526,193, filed on March 15, 2000. Certain references were submitted to the Office in the prior application and, therefore, are not provided in this application. A copy of the previously submitted form PTO-1449 from the parent application is enclosed.

If there are any other charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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Sheet _1_ of SUBSTITUTE FORM PROMERON び.S. DEPARTMENT OF COMMERCE Attorney Docket No. 50110/002005 (MODIFIED) PATENT AND TRADEMARK OFFICE Serial No. 09/526,193 Applicant Michael R. Hayden et al. INFORMATION DISCLOSURE STATEMENT BY APPLICANT Filing Date March 15, 2000 (Use several sheets if necessary) Group (37 CFR §1.98(b)) **IDS Filed** November 6, 2000 **U.S. PATENTS** Examiner's Patent Number Issue Date Patentee Class Subclass Filing Date (If Appropriate) Initials FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION Examiner's Document . Publication Country or Class Subclass Translation Patent Office Initials Number Date (Yes/No) WO 98/37764 03.09.98 PCT WO 98/51351 19.11.98 **PCT** WO 00/18912 06.04.00 **PCT** WO 99/31133 24.06.99 PCT OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) Allikmets et al., "Organization of the ABCR Gene: Analysis of Promoter and Splice Junction Sequences," Gene 215:111-122 (1998). Allikmets et al., "Characterization of the Human ABC Superfamily: Isolation and Mapping of 21 New Genes Using the Expressed Sequence Tags Database," Hum. Mol. Genet. 5:1649-1655 (1996). Bodzioch et al., "The Gene Encoding ATP-binding Cassette Transporter 1 Is Mutated in Tangier Disease," Nat. Genet. 22:347-351 (1999). Borst P., "Multidrug Resistant Proteins," Semin. Cancer Biol. 3:131-134 (1997). Brooks-Wilson et al., "Mutations in ABC1 in Tangier Disease and Familial High-density Lipoprotein Deficiency," Nat. Genet. 22:336-345 (1999). Dean et al., "Evolution of ATP-binding Cassette Transporter Genes," Curr. Opin. Gen. Dev. 5:779-785 (1995). Drobnick et al., "Activation of Phosphatidylinositol-Specific Phospholipase C in Response to HDL Sub 3 and LDL is Markedly Reduced in Cultured Fibroblasts From Tangier Patients," Arterioscler. Thromb. Vasc. Biol. 15:1369-1377 (1995). Kuivenhoven et al., "Heterogeneity at the CETP Gene Locus: Influence on Plasma CETP Concentrations and HDL Cholesterol Levels," Arterioscler. Thromb. Vasc. Biol. 17:560-568 (1997). Langmann et al., "Molecular Cloning of the Human ATP-Binding Cassette Transporter 1 (hABC1): Evidence for Sterol-Dependent Regulation in Macrophages," Biochemical and Biophysical Research Communications 257:29-33 (1999). Lawn et al., "The Tangier Disease Gene Product ABC1 Controls the Cellular Apolipoprotein-mediated Lipid Removal Pathway," J. Clin. Invest. 104:R25-R31 (1999). Luciani et al., "Cloning of Two Novel ABC Transporters Mapping on Human Chromosome 9," Genomics 21:150-159 (1994). Marcil et al., "Cellular Cholesterol Transport and Efflux in Fibroblasts Are Abnormal in Subjects With Familial HDL Deficiency," Arterioscler. Thromb. Vasc. Biol. 19:159-169 (1999). **EXAMINER** DATE CONSIDERED

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Sheet 2 of 2 DEPARTMENT OF COMMERCE Attorney Docket No. 50110/002005 SUBSTITUTE FORM (MODIFIED) Serial No. 09/526,193 Applicant Michael R. Hayden et al. INFORMATION DISCLOSURE STATEMENT BY APPLICANT Filing Date March 15, 2000 (Use several sheets if necessary) Group **IDS Filed** November 6, 2000 (37 CFR §1.98(b)) U.S. PATENTS Class Subclass Filing Date Examiner's Patent Number Issue Date Patentee Initials (If Appropriate) FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION Examiner's Document Publication Class Subclass Translation Country or Initials Number Date Patent Office (Yes/No) OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) Remaley et al., "Human ATP-binding Cassette Transporter 1 (ABC1): Genomic Organization and Identification of the Genetic Defect in the Original Tangier Disease Kindred," Proc. Natl. Acad. Sci. U.S.A. 96:12685-12690 (1999).Rogler et al., "HDL-Mediated Efflux of Intracellular Cholesterol Is Impaired in Fibroblasts From Tangier Disease Patients," Arterioscler. Thromb. Basc. Biol. 15:683-690 (1995). Rust et al., "Assignment of Tangier Disease to Chromosome 9q31 by a Graphical Linkage Exclusion Strategy," Nature Genetics 20:96-98 (1998). Rust et al., "Tangier disease is caused by mutations in the gene encoding ATP-binding cassette transporter 1," Nature Genetics 22:352-355 (1999). Savary et al., "Isolation and Chromosomal Mapping of a Novel ATP-binding Cassette Transporter Conserved in Mouse and Human," Genomics 41:275-278 (1997). Schmitz et al., "ATP-binding Cassette Transporter A1 (ABCA1) in Macrophages: A Dual Function in Inflammation and Lipid Metabolism?," Pathobiology 67:236-240 (1999). Wilson et al., "2.2 Mb of Contiguous Nucleotide Sequence From Chromosome III of C. Elegans," Nature 368:32-38 (1994). GenBank Accession No. AF165281 GenBank Accession No. P41233 GenBank Accession No. NM 005502 GenBank Accession No. X75926 GenBank Accession No. A54774 GenBank Accession No. AAC69223 GenBank Accession No. CAA10005 GenBank Accession No. AJ012376 **EXAMINER** DATE CONSIDERED EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this

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50110/004002 SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE Attorney Docket No. PATENT AND TRAVEID HKOFFICE (MODIFIED) 09/654.323 Serial No. Michael R. Hayden et al. EIVED Applicant INFORMATION DISCLOSURES STATEMENT BY APPLICANT September 1, 2000 DEC 0 8 2000 Filing Date STATEMENT BY APPLICANT (Use several sheets if necessary) Group November 29,7200PCENTER 600/2900 **IDS Filed** (37 CFR §1.98(b)) FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION Translation Class Subclass Publication Country or Document Examiner's (Yes/No) Patent Office Number Date Initials **PCT** WO 98/37764 03.09.98 **PCT** WO 98/51351 19.11.98 PCT 06.04.00 WO 00/18912 PCT WO 99/31133 24.06.99 OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) Allikmets et al., "Organization of the ABCR Gene: Analysis of Promoter and Splice Junction Sequences," Gene 215:111-122 (1998). Allikmets et al., "Characterization of the Human ABC Superfamily: Isolation and Mapping of 21 New Genes Using the Expressed Sequence Tags Database," Hum. Mol. Genet. 5:1649-1655 (1996). Apfel et al., "A novel orphan receptor specific for a subset of thyroid hormone-responsive elements and its DJS interaction with the retinoid/thyroid hormone receptor subfamily," Molecular and Cellular Biology 14:7025-7035 (1994).Bodzioch et al., "The Gene Encoding ATP-binding Cassette Transporter 1 Is Mutated in Tangier Disease," Nat. Genet. 22:347-351 (1999). Borst P., "Multidrug Resistant Proteins," Semin. Cancer Biol. 3:131-134 (1997). Brooks-Wilson et al., "Mutations in ABC1 in Tangier Disease and Familial High-density Lipoprotein Deficiency," Nat. Genet. 22:336-345 (1999). Dean et al., "Evolution of ATP-binding Cassette Transporter Genes," Curr. Opin. Gen. Dev. 5:779-785 (1995). Drobnick et al., "Activation of Phosphatidylinositol-Specific Phospholipase C in Response to HDL Sub 3 and LDL is Markedly Reduced in Cultured Fibroblasts From Tangier Patients," Arterioscler. Thromb. Vasc. Biol. 15:1369-1377 (1995). Janowski et al., "An oxysterol signalling pathway mediated by the nuclear receptor LXRa," Nature 383:728-731 Kuivenhoven et al., "Heterogeneity at the CETP Gene Locus: Influence on Plasma CETP Concentrations and HDL Cholesterol Levels," Arterioscler. Thromb. Vasc. Biol. 17:560-568 (1997). Langmann et al., "Molecular Cloning of the Human ATP-Binding Cassette Transporter 1 (hABC1): Evidence for Sterol-Dependent Regulation in Macrophages," Biochemical and Biophysical Research Communications 257:29-33 (1999). Lawn et al., "The Tangier Disease Gene Product ABC1 Controls the Cellular Apolipoprotein-mediated Lipid Removal Pathway," J. Clin. Invest. 104:R25-R31 (1999). Lehmann et al., "Activation of the nuclear receptor LXR by oxysterols defines a new hormone response pathway," Journal of Biological Chemistry 272:3137-3140 (1997). DATE CONSIDERED **EXAMINER** EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this

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TITUTE FORM PTO 349 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50110/004002
DEC 0 4 2000	Serial No.	09/654,323
INFORMATION DISCLOSURE	Applicant	Michael R. Hayden et al.
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(37 CFR §1.98(b))			IDS Filed	November 8, 2000	
	OTHER DOCUMENTS (INCLUDING AUTHOR	R, TITLE, D	ATE, PLACE OF PUBL	ICATION)	
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	Remaley et al., "Human ATP-binding Cassette Transporter 1 (ABC1): Genomic Organization and Ic of the Genetic Defect in the Original Tangier Disease Kindred," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 96 :126 (1999).				
	Rogler et al., "HDL-Mediated Efflux of Intracellular Cholesterol Is Impaired in Fibroblasts From Tangier I Patients," Arterioscler. Thromb. Basc. Biol. 15:683-690 (1995).				
	Rust et al., "Assignment of Tangier Disease to Chromosome 9q31 by a Graphical Linkage Exclusion Strategy Nature Genetics 20:96-98 (1998).				
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	Savary et al., "Isolation and Chromosomal Mapping of a Novel ATP-binding Cassette Transporter Conserved in Mouse and Human," <i>Genomics</i> 41 :275-278 (1997).				
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